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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,965	01/12/2001	Matthew Thomas Heisey	8398	1681

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EXAMINER

CRANE, LAWRENCE E

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>	
	09/759,965	HEISEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 Dec 2002 (brief).
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,7-9,11,12 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-9,11,12 and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>12</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

The Notice of Appeal is held in abeyance and prosecution on the merits of this application is reopened on claims **1-2, 4, 7-9, 11-12 and 43** which are considered unpatentable for the reasons indicated below.

Claims **3, 5-6, 15 and 17-18** have been cancelled, claims **1, 4, 13, 16, 19 and 36** have been amended, and no new claims have been added as per the amendment filed October 8, 2002 the entry of which was indicated as acceptable by Examiner in paper no. 15 (Advisory Action, mailed October 22, 2002) following filing by Appellant of a Notice of Appeal and an Appeal Brief. A Terminal Disclaimer filed October 8, 2002 has been found acceptable and entered. No additional Information Disclosure Statements (IDSs) have been received as of the mailing date of this Office action.

Claims **1-2, 4, 7-9, 11-12 and 43** remain in the case.

The disclosure is objected to because of the following informalities:

Incorporation by reference of essential material by reference to a foreign application or a foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by applicant, or a practitioner representing applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

In each of the above cases, the incorporations are of the complete document, and fails to properly point out the particular portions of the US patent(s) being incorporated; see MPEP §608.01(p)(1)(A) noting *In re de Seversky* and in the same paragraph (column 2 of p. 600-769, August 2001 edition) the instruction which reads as follows: “[p]articular attention should be directed to specific portions of the referenced document wherein the subject matter being incorporated may be found.”

The attempt to incorporate subject matter into this application by reference at page 4, lines 23-24 to "all references cited herein are incorporated by reference" is improper because applicant has failed to meet the requirement of the *Hawkins* decisions noted supra.

Appropriate correction is required.

Claims 1-2, 4, 7-9, 11-12 and 43 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1 the terms "cartilage," "aminosugars," and "glycosaminoglycans" are directed to a vast array of compounds only a few of which are known to have the desired beneficial effects claims. The remainder of the specific compounds included within the generic terms noted are not properly described within the instant written description.

Applicant's arguments filed December 23, 2002 have been fully considered but they are not persuasive.

Applicant argues in the appeal brief at beginning at page 6 that the terms chosen include compounds with different levels of efficacy but does not admit that any of these additional undisclosed compounds lack the desired pharmaceutical effect; i.e. that the entire generic class of compounds encompassed by the noted generic terms is active. However, applicant cites no authority or factual basis for this assertion. Examiner admits on the instant record that glucosamine, cartilage, chondroitin, methylsulfonylmethane and S-adenosylmethionine are each known individually and in mixtures to be effective agents to assist in the treatment of arthritis. However, in the absence of data to the contrary, examiner argues that the great breadth of the generic terms is excessive because applicant has failed to provide the requisite guidance for the ordinary practitioner to determine the key component part or parts required of each member of each generic class for said member to have the claimed efficacy. Therefore, this argument is deemed to be an inadequate response and for this reason not a proper basis for withdrawal of the instant rejection must possess in order to be a member of the class of compounds

Claims **1 and 2** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of “undue experimentation” is appropriate are as follows:

A. The breadth of the claims is very large because of reliance in the claims on generic terms including “cartilage,” “aminosugars,” “glycosaminoglycans,” and “mixtures thereof” which are directed to a vast array of different oligomeric and polymeric substances.

B. The nature of the invention is directed to beverage compositions which have utility in the treatment of joint dysfunctions including arthritis.

C. The state of the prior art is well developed as revealed by the very long lists of prior art citations provided by applicant and by examiner, but are limited in the specific exemplifications to the administration of compositions containing the specific compounds glucosamine, chondroitin, methylsulfonylmethane and S-adenosyl methionine or subsets thereof. Examiner notes Table 10-2 in the newly cited **Lehninger** reference (PTO-892 ref. **W**) which identifies the chemical contents of naturally saccharide and oligosaccharides found in mammals, a disclosure which raises the question of whether compounds other than glucosamine and chondroitin are effective sources of the molecular building blocks necessary to permit the mammalian joint-related tissues to be repaired *in vivo* by the instant compositions as suggested by instant claim **43** wherein administration instructions are provided.

D. The level of one of ordinary skill is high in light of the very large number of references which provide very substantial guidance concerning how to administer nutritive and non-nutritive compositions containing glucosamine, chondroitin, methylsulfonylmethane, cartilage and S-adenosyl methionine to effect the *in vivo* repair of mammalian joint tissues. However, the level of skill of the ordinary practitioner is very low when other members of the genus aminosugars and the genus glucosaminoglycans are substituted for glucosamine and chondroitin, respectively.

E. The level of predictability in the art is very high when glucosamine, chondroitin, methylsulfonylmethane, cartilage and S-adenosyl methionine are the active ingredients, but becomes very low when other members of the genus aminosugars and the genus glucosaminoglycans are substituted for glucosamine and chondroitin, respectively.

F. The amount of direction provided by the inventor is limited to two examples with some analysis of the prior art in support of the substantial array of molecules and extracts which are found within the carrier.

G. The existence of working examples is limited to two examples and these examples are directed only to composition preparation, and do not include any medicinal testing data.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be very low if the active ingredients are limited to glucosamine, chondroitin, methylsulfonylmethane, cartilage and S-adenosyl methionine, but becomes exceptionally high when the vast arrays of other members of the genus aminosugars and the genus glucosaminoglycans are substituted for glucosamine and chondroitin, respectively. Examiner therefore concludes that limitation of the instant claims to glucosamine and chondroitin is therefore an appropriate way to avoid a clear case of undue experimentation.

Applicant's arguments with respect to claims **1-2, 4, 7-9, 11-12 and 43** have been considered but are moot in view of the new grounds of rejection.

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

"A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

Claims **1-2, 4, 7-9, 11-12 and 43** are rejected under 35 U.S.C. §103(a) as being unpatentable over **Nutramax Laboratories '816** (PTO-1449 ref. CA) in view of **Florio '715** (PTO-1449 ref. BF), **Martino '692** (PTO-1449 ref. BM), **Burger '919** (PTO-14549 ref. BG), **Murad '594** (PTO-1449 ref. BE), and **Herschler '878** (PTO-1449 ref. AU) and further in

view of **applicant's own admissions**, **Vanderveen et al.** (PTO-892 ref. U) and **Swinyard et al.** (PTO-892 ref. V).

The instant claims are directed to beverage (liquid) compositions containing cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adenosyl methionine and numerous additional nutritional and non-nutritional additional ingredients and carriers for the purpose of treating arthritis, and a kit for this specific purpose including written instructions for the administration/consumption of the composition to, or by, an end user in need thereof.

**Nutramax Laboratories '816** (PTO-1449 ref. CA) discloses the administration of compositions including glucosamine, chondroitin, and optionally various vitamins and minerals (nutrients) for the treatment of arthritis in mammals.

**Florio '715** (PTO-1449 ref. BF) discloses the administration of compositions including glucosamine, chondroitin, and optionally lipids/fatty acids in liquid form including administration instructions for the treatment of arthritis in mammals.

**Martino '692** (PTO-1449 ref. BM) discloses the administration of compositions including cartilage, glucosamine, chondroitin, and optionally various nutrients for the treatment of arthritis in mammals.

**Burger '919** (PTO-1449 ref. BG; also specifically cited by applicant's disclosure) discloses the administration of compositions including glucosamine, and optionally lipids/fatty acids for the treatment of arthritis in mammals.

**Murad '594** (PTO-1449 ref. BE) discloses the administration of compositions including glucosamine, chondroitin, and optionally nutrients including vitamins and minerals for the treatment of arthritis in mammals.

**Herschler '878** (PTO-1449 ref. AU) discloses the administration of compositions including methylsulfonylmethane, and optionally as part of a nutrient (food) for the treatment of arthritis in mammals.

**Applicant's own admissions:** at page 1, original lines 12-13, applicant admits that the prior art teaches the effectiveness of glucosamine and chondroitin in the treatment of osteoarthritis (hereinafter "arthritis"). Applicant also admits in the same paragraph that

numerous commercial products in this art area are readily formulated into beverage compositions immediately prior to consumption. At the top of page 2, applicant further admits that “[c]hondroprotective agents may be delivered in the form of compositions having high sugar content.” Applicant also admits at page 11, last full paragraph, that methylsulfonylmethane is known in the prior art to have been administered to treat arthritis. Applicant admits at page 12, three lines from the bottom of the page, that “[s]weetening agents are commonly known in the art,” and at lines 9-11 of page 12 also admits that certain naturally occurring sweeteners are well known in that art. At the top of page 14, applicant also admits that other commercially available sweeteners including “saccharin” are well known in the art.

**Vanderveen et al.** (PTO-892 ref. U) in chapter 51 of Remington’s Pharmaceutical Sciences, 18th Edition, entitled “Vitamins and Other Nutrients,” discloses a long list of substances normally found in food stuffs including the nutrients “glucose,” “fats and oils,” and “fructose.”

**Swinyard et al.** (PTO-892 ref. V) in chapter 66 of Remington’s Pharmaceutical Sciences, 18th Edition, entitled “Pharmaceutical Necessities,” discloses numerous substances included within the instant claims including generically “flavoring agents” including “saccharin,” “cherry juice,” “raspberry juice,” and “sucrose,” “Vehicles” and “Diluting Agents” including water, “Emulsifying and Suspending Agents,” “Pharmaceutical Solvents” including “water,” and “Miscellaneous Pharmaceutical Necessities” including “lactose.”

Applicant’s disclosure does not provide any showing of unexpected results. Therefore, applicant has merely provided directions for the admixing of active ingredients of known pharmaceutical activity (cartilage, glucosamine, chondroitin, methylsulfonylmethane, and S-adenosyl methionine) each of which has been included in one or more of the cited prior art compositions which are asserted repeatedly in the prior art to be effective in the treatment of arthritis. These pharmaceutical activities are each also admitted by applicant’s own disclosure. The additional components of the claimed composition are also well known in the art and are not asserted to be anything other than carriers or pharmaceutical necessities and/or nutrients several of which are specifically listed in the cited art, and none of which are asserted by applicant to represent a critical feature for any final composition. The presence of instructions directed to the end user is also a feature known in the prior art cited above (see ref. **BF**).



In light of applicant's failure to provide any data to support an unexpected benefit from the instant claimed compositions, the instant claimed compositions, kits thereof and methods of administration thereof, are deemed to lack patentable distinction as being nothing more than a mixture of substances known in the prior art as anti-arthritis agents and therefore obvious compositions to be administered to a host in need thereof. Any additional compounds acting in concert has the carrier or excipient (e.g. sweeteners, etc., etc.) have been included in the spirit of making the resultant composition palatable and optionally nutritious as admitted by applicant's own disclosure, and as generically taught by the Vanderveen and Swinyard disclosures.

Therefore, the instant claimed compositions, and kits with instructions directed to methods of administration would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **1-2, 4, 7-9, 11-12 and 43** have been considered but are moot in view of the new grounds of rejection.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 703-872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

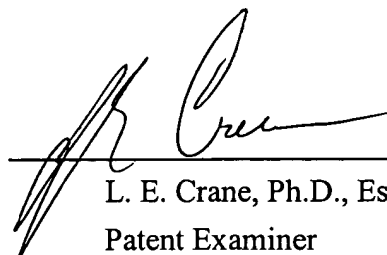
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached at **571-272-0661**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

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LECrane:lec  
05/03/2004

A handwritten signature in black ink, appearing to read "L. E. Crane", is written over a horizontal line.

L. E. Crane, Ph.D., Esq.  
Patent Examiner  
Technology Center 1600